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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HBC 255-KFM

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EXAMINER

RAMDHANIE, BOBBY

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,034	Applicant(s) KRATZER ET AL.	
	Examiner BOBBY RAMDHANIE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/28/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-4, & 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended the claims submitted on 08/08/2006 to specifically recite that the claim is to an improvement of a device. It is unclear to the Examiner how further detailing the structure of the device AND NOT the improvement further defines the improvement.

3. Claims 12 & 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the limitations in these dependent claims are towards the device or the improvement (which is also claimed as a device).

4. Claim 9 recites the limitations "the slot shaped opening" & "the stirring rod part" in Claim 1. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 17 recites the limitation "the rod part" in Claim 15. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 13 recites the limitations "the small suction tube," "the capillary," "the opening," and "the ring part" in Claim 6. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Boyd et al (WO99/39182).

9. Applicants' claim is toward a device.

10. Regarding Claim 1, Boyd et al discloses in a flow-through device for measuring the platelet function of primary hemostasis, the aggregation and/or the coagulation and/or the viscosity of the blood, with a reservoir, which is disposed in a housing, and from which blood can be taken for the measurement and conveyed through an aperture, the improvement comprising: A stirring device arranged in the reservoir and moved in such a manner, that a stirrer part of the stirring device thoroughly mixes the blood in the reservoir during the measurement and keeps it in motion (See Page 14 lines 14-20). Applicant is claiming an improvement to a device – the improvement being the stirring device located in a reservoir. Boyd discloses this feature. The reservoir being the cuvette and the stirring mechanism being a stirring device which is capable of performing the same function or intended use).

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11. Claims 1, 5-7, 9, & 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bote Bote (WO03/087817; An English translation may be found as US7361306).

12. Applicants' claim is toward a device.

13. Regarding Claims 1, 5-7, 9, & 15-17, Bote Bote discloses in a flow-through device for measuring the platelet function of primary hemostasis, the aggregation and/or the coagulation and/or the viscosity of the blood, with a reservoir, which is disposed in a housing, and from which blood can be taken for the measurement and conveyed through an aperture, the improvement comprising: A stirring device (See Figure 1 Item 2 (rotor defines a stirring device) arranged in the reservoir (See Figure 1 Item 1) and moved in such a manner, that a stirrer part of the stirring device thoroughly mixes the blood in the reservoir during the measurement and keeps it in motion.

14. Additional Disclosures Included: Claim 5: The stirrer part of the stirring device in the reservoir is disposed on a stirring rod, which extends in the longitudinal direction of the housing and can be moved in the longitudinal direction of the housing by a driving mechanism (See Figure 1 Item 2, the rotor is rotated in the longitudinal direction by an electric motor Item 8); Claim 6: The device of Claim 1, wherein the stirrer part has the shape of a circular disk (See Figure 1 Item 2, the rotor has a circular shape); Claim 7: The stirrer part extends essentially perpendicularly to the longitudinal direction of the housing (See Figure 1); Claim 9: The housing has a further curved projection which extends in the longitudinal direction of the housing and opens up into the reservoir (See Figure 1 side walls, the walls are curved outward), wherein the stirring rod part (See

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Figure 1, cylinder which it attached to the rotor) is disposed in the further curved projection in the region of the reservoir (See Figure 1), and wherein the slot-shaped opening is disposed in the curved projection and above the reservoir (See Figure 1 Item 3, this area may define a slot shaped opening and is above the reservoir); Claim 15: The device of Claim 1, wherein the stirring device in the region of the blood supply of the reservoir, has no contact with stationary surfaces of the wall surroundings of the reservoir, so that squeezing of blood cells or other components of the blood can be prevented and substances, which are undesirably released and could lead to distortion of the results of the measurements, do not reach the blood (See Figure 1 Item 2 has no contact with the reservoir); Claim 16: The stirrer part of the stirring device is mounted and can be moved in the reservoir without contacting the latter (See Figure 1) and Claim 17: The rod part of the stirring device is mounted and can be moved in the further curved projection without contacting it (See Figure 1 cylinder which mounts the rotor, the cylinder rotates with the rotor).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1-4, 8, 10-12, & 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kratzer et al (US6159741) in view of Boyd et al (WO9939182).

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17. Applicants' claims are toward a device.

18. Regarding Claims 1-4, 12, & 14, Kratzer et al discloses in a flow-through device for measuring the platelet function of primary hemostasis, the aggregation and/or the coagulation and/or the viscosity of the blood, with a reservoir, which is disposed in a housing, and from which blood can be taken for the measurement and conveyed through an aperture. Kratzer et al does not disclose, the improvement comprising: A stirring device arranged in the reservoir and moved in such a manner, that a stirrer part of the stirring device thoroughly mixes the blood in the reservoir during the measurement and keeps it in motion. Boyd et al discloses the improvement comprising: A stirring device arranged in the reservoir and moved in such a manner, that a stirrer part of the stirring device thoroughly mixes the blood in the reservoir during the measurement and keeps it in motion (See Page 14 lines 14-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kratzer et al with the stirring mechanism as suggested by Boyd et al in order to prevent the aperture at the bottom of the reservoir in Kratzer et al from clogging, the blood components from separating out during analysis and therefore providing erroneous results.

19. Additional Disclosures Included: Claim 2: The housing has a cylinder and a piston disposed therein (See Kratzer et al Figure 4 Items 22 & 24), and wherein the aperture is disposed in the bottom wall of the cylinder, through which the blood from the reservoir can be passed during a corresponding movement of the piston (See Figure 4 Items 29 (Item 29 labeled as an aperture or Item 45 also has an aperture); Claim 3:

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The housing has an opening region, through which the blood can be filled in to the reservoir of the housing (See Kratzer et al Figure 4 Item 21); Claim 4: The opening region is in the shape of a curved projection of the housing, which is surrounded by the socket-shaped, outwardly inclined side wall region of the housing (See Kratzer et al; Figure 4); Claim 12: A small suction tube or a capillary, which extends into the reservoir, precedes the aperture and that the blood can be conveyed from the reservoir through the small suction tube or the capillary to the aperture (See Figure 5 Item 45); and Claim 14: It is constructed as a disposable part (See Column 4 lines 63-67).

20. Claims 8, 10, & 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bote Bote.

21. Applicants' claims are toward a device.

22. Regarding Claim 8, Bote Bote discloses the device of Claim 5 wherein the stirring rod protrudes through a slot shaped opening (See Figure 1, cylinder which is attached to the rotor protrudes through the reservoir bottom), which extends in the longitudinal direction of the housing, radially to the outside and can be moved by the driving mechanism, so that the stirrer part can be moved back and forth in the longitudinal direction of the housing in the interior of the reservoir (See Figure 1). Bote Bote does not disclose that its side averted from the stirrer part, has a step part. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the cylinder to have a step part which is averted from the stirrer part, to form a

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seal between the bottom of the reservoir and the cylinder shaft to prevent the fluid from leaking through the bottom.

23. For Claim 10, Bote Bote discloses the device of claim 9, except wherein the further curved projection has a rectangular cross section. Bote Bote does however disclose that the curved projection has a diametrical conduit (See Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the diametrically designed curved projection to be rectangular to accommodate a syringe because according to Bote Bote this curved projection is where the blood sample is deposited.

24. Additional Disclosures Included: Claim 11: The further curved projection is disposed opposite to the curved projection (Examiner interprets this limitation as diametrically opposed sides that are the same).

25. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bote Bote in view of the combination of Kratzer et al and Boyd et al.

26. Applicants' claims are toward a device.

27. Regarding Claim 13, Bote Bote discloses the device of Claim 6, except wherein the small suction tube or the capillary extends through the opening of the ring part. The Combination of Kratzer et al and Boyd et al discloses the small suction tube or the capillary extends through the opening of the ring part (See Kratzer et al Figure 5 Item 45 – tube which extends through the ring part (Figure 5 Item 27). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify

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Bote Bote with the combination of Kratzer et al and Boyd et al because this would allow the sample to be placed in the inner curved projection which is above the reservoir using a syringe.

Telephonic Inquiries

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. R./

/Walter D. Griffin/

Supervisory Patent Examiner, Art Unit 1797